

## EXTENDED REPORT

## Impact of musculoskeletal disorders on quality of life: an inception cohort study

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**Objective:** To assess longitudinally the impact of new onset musculoskeletal (MSK) disorders on quality of life (QoL).

**Methods:** An inception cohort of 1202 subjects in France aged 45–60 years was determined to be free of MSK problems at baseline. Over 28 months of follow up between 1996 and 1998, 310 were diagnosed with MSK disorders and matched for age and sex with 620 healthy controls. The impact of the MSK disorder onset on QoL was assessed by the change in SF-36 dimension scores over time, using a linear mixed ANOVA model to compare the groups.

**Results:** The incidence of MSK disorder was 13.6% per person-year in the spine, 4.2% per person-year in a joint, and 4.6% per person-year at an extra-articular site. The greatest change in QoL was a 10 point drop in the 100 point SF-36 bodily pain dimension scale in the MSK group. Compared with controls, subjects with an MSK disorder had significantly greater reductions in the following dimensions: bodily pain ( $\alpha$  –7.4 point difference in change), vitality (–2.7), general health (–1.8), and physical functioning (–1.3). Within the MSK group, chronic disorders had a greater impact than acute ones on the physical functioning (–2.1), role emotional (–8.4), and social functioning (–5.9) dimensions.

**Conclusion:** New onset MSK disorders have a marked deleterious effect on QoL in the physical domain, with lesser effects on social and mental functioning. This evidence of an early significant impact on their QoL reinforces recent recommendations for early treatment and primary prevention.

Quality of life (QoL) is an important indicator of the burden of musculoskeletal (MSK) disease.<sup>1</sup> The pattern and magnitude of the effect of MSK conditions on QoL are best assessed longitudinally in an inception cohort, ensuring that baseline data are collected before the condition has occurred. Because longitudinal studies in this area have included subjects with existing disorders (that is, patients in observational or interventional trials), little is known about the true impact of such illness on previously healthy subjects.<sup>2–4</sup> Most investigations examining the potential drop in QoL induced by MSK disorders have compared patients with established disease with healthy controls in a cross sectional design.<sup>5–6</sup> The difference between groups can provide some information about the existence and amount of any effect on QoL, but methodological problems limit the conclusions that can be drawn.

A group of subjects with no MSK problems during the follow up period is required to control for the natural evolution of QoL over time. Age and sex matching is necessary because most relevant QoL dimensions decrease with age in adults<sup>7</sup> and are consistently lower in women than in men throughout adult life. Use of appropriate controls allows for assessment of time related variation in QoL, comparison between patients with MSK disorders and healthy subjects, and specific evaluation of QoL changes related to MSK disorders.

The goal of the present study is to test the hypothesis that people who develop an MSK disorder have a significant change in subsequent QoL compared with controls matched for age and sex. The nature of MSK illness, whether it is chronic or acute, and the influence of any comorbidities are taken into account. Unlike previous investigations, disorder-free baseline QoL data are available for all subjects.

## MATERIAL AND METHODS

## Design of the SU.VI.MAX quality of life study

Subjects were drawn from the study population of the SU.VI.MAX trial, a large, randomised, placebo controlled longitudinal investigation initiated in France in 1994 to quantify possible preventive effects of antioxidants, vitamins, and minerals in a general population of women aged 35–60 years and men 45–60 years.<sup>8</sup> The characteristics of the participants are close to those of the national population, which allows generalisation of the results to the French adult population. SU.VI.MAX subjects of both sexes aged 45–60 years at entry, who underwent clinical examination in 1996 and completed QoL questionnaires in 1996 and 1998, were eligible for the present quality of life study. Questionnaires were mailed to respondents biennially, and returned at the subsequent clinical examination.

Of 4882 subjects invited to take part in the quality of life study, 3759 were eligible for inclusion, while 1123 did not complete QoL questionnaire at both measurement times. Subjects who did not complete follow up of the quality of life study were still followed up on the SU.VI.MAX trial. They represented 23% of the initial sample and did not show differences in age, sex and comorbidity characteristics from those with QoL data available at follow up. Among eligible subjects 2557 presented with MSK at baseline, leaving a study sample of 1202 MSK disorder-free subjects forming an inception cohort. On the basis of clinical examinations, Minitel telematic network (a small terminal widely used in France as an adjunct to the telephone) and postal declarations over time, they were assigned to one of two groups at the end of follow up:

**Abbreviations:** ANOVA, analysis of variance; MSK, musculoskeletal; QoL, quality of life; SF-36, Short Form-36

- Subjects who developed an MSK disorder during follow up (MSK disorder group)
- Subjects who remained free of an MSK disorder throughout (MSK disorder-free group).

A random selection process was used to age (+/- 1 year) and sex match each subject in the MSK disorder group with two subjects in the MSK disorder-free group. The aim of matching was to control for the potentially confounding effects of age and sex on the relationship between onset of a MSK disorder and QoL.

### QoL assessment

QoL was assessed using a validated French translation<sup>9</sup> of the Short Form-36 (SF-36) generic questionnaire,<sup>10</sup> a widely used general health status measure. SF-36 consists of 36 items divided into eight dimensions of health. Each dimension is scored from 0 (worst) to 100 (best possible health status).<sup>7</sup>

SF-36 has been applied in general population surveys in many countries and age groups, and used for specific MSK diseases, including rheumatoid arthritis and osteoarthritis.<sup>5</sup> SF-36 scores were used to derive utility values, by computing SF-6D scores according to a recently proposed algorithm.<sup>11</sup>

### Morbidity assessment

Sociodemographic and morbidity data were obtained by questionnaire at baseline. Details of prior medical events, including rheumatic disorders (back pain, neck pain, thoracic pain), non-rheumatic disorders such as cardiovascular disease, cancer, diabetes, infectious disease requiring antibiotic administration, digestive disorder, asthma, and miscellaneous conditions were recorded. In addition, an open question allowed free wording to report health problems.

Medical follow up included (a) monthly self reports by mail or Minitel of any new diseases or symptoms (pain, swelling, stiffness, invalidity...), related medical consultations, admissions to hospital, and treatments; (b) a clinical visit every second year at which physicians of subjects with major health events of any kinds were contacted to confirm the diagnosis. Investigations were made if the Minitel connection was broken for a long period of time, or if a participant failed to keep a follow up appointment.

Most answers collected were symptoms: tendonitis, disc herniation, back pain, neck pain. MSK diagnosis was exceptional.

Criteria for classification were built up according to location of disorders:

- *Spinal disorder*: back pain, neck pain, diffuse spine pain, disk herniation, vertebral osteoporosis
- *Joint disorder*: osteoarthritis (spine excluded), microcrystalline arthritis, arthritis (joint pain, rheumatism)
- *Extra-articular disorder*: capsulitis, tendinopathy, carpal tunnel syndrome, muscular pain.

The criteria were tested by a subsample analysis by two rheumatologists blinded to each other (CHR, FG), and further resolving discrepancy by consensus. One rheumatologist (CHR) completed the whole sample analysis. Difficult cases, ambiguous wording were solved jointly.

There was no bar to a single subject reporting several MSK disorders during follow up. Because conditions that fell into different categories were classified and counted as such, the number of disorders could exceed the number of subjects.

A distinction was made between acute and chronic disorders, based on the frequency of (and time interval between) reports. MSK disorders were considered acute when reported once or more over less than 3 months. Acute relapsing disorders were those reported twice, with more than 3 months between the first and second reports, and were taken into account as acute disorders. Conditions reported three or more times over more than 3 months were recorded as chronic.

### Analysis of data

Subject characteristics were recorded using means and standard deviation (SD) or percentages. Groups were compared at baseline for sociodemographic characteristics, QoL scores, and comorbidity using the  $\chi^2$  test for qualitative variables, Student's *t* test, and analysis of variance (ANOVA) for quantitative variables. QoL scores were computed in every SF-36 dimension as recommended by the developer.<sup>10</sup>

The incidence of MSK disorders was calculated by person-years of exposure until the first report in each category. Acute (unique or relapse) and chronic disorders were reported separately.

The impact of onset of an MSK disorder on the way in which QoL changes over time was estimated by comparing the change in QoL score from baseline to follow up between the two groups. The analysis took account only of the first occurrence of a chronic MSK disorder (that is, the earliest in the follow up), and the last occurrence of an acute condition (that is, the most recent).

Baseline univariate analysis was used to identify variables that varied significantly between the two groups, and subsequent multivariate analysis using a linear mixed ANOVA model was then adjusted for those and matching variables. This approach allowed repeated measurement of the dependent variable—that is, QoL scores, and provided an estimate of the effect of independent variables, such as onset of an MSK condition, to be expressed as mean scores adjusted on covariates. The difference in QoL change between groups was estimated by testing the significance of the interaction term of MSK occurrence with group over time effect (repeated measurement). MSK disorders were tested both overall and by category (spine, joint, and extra-articular). In addition, an analysis was conducted within the group with MSK disorder to test for the effect on QoL of acute (unique or relapse) versus chronic conditions. If a subject reported both acute and chronic disorders, only the latter were considered. This ANOVA model was applied to the

**Table 1** Baseline characteristics of subjects with a musculoskeletal (MSK) disorder and age and sex matched MSK disorder-free controls

Characteristics	MSK disorder (n=310)	MSK disorder-free (n=620)	p Value
Age (years), mean (SD)	51.1 (4.3)	51.1 (4.3)	—†
Women	37	37	—†
Living alone	13	9	0.07
Professional status			0.42
Professionals	7	9	
Managerial	59	54	
Workers	15	15	
Unemployed/retired	19	22	
Education level			0.48
Primary	35	38	
Secondary	25	26	
Tertiary	40	36	
Comorbidity			
Cancer	3	1	0.08
Infectious disease‡	14	6	0.0001
Diabetes	0.7	1	0.50
Cardiovascular	5	3	0.14
Antioxidant supplementation	49.4	51.1	0.26

Results are percentages unless otherwise stated.

\*Standard deviation; †matching variables; ‡infectious disease requiring antibiotic treatment.

**Table 2** Musculoskeletal (MSK) disorders reported

	Total			Acute No	Chronic No
	No	Incidence*	95% CI		
Spine disorders	230	13.6	12.0 to 15.3	173	57
Neck pain	46	3.1	2.3 to 4.0	30	16
Back pain	135	8.5	7.2 to 9.9	106	29
Disk herniations	51	3.4	2.5 to 4.4	37	14
Osteoporosis (stress fractures)	5	0.3	0.1 to 0.6	4	1
Spine diffuse	12	0.8	0.4 to 1.3	12	0
Joints disorders	63	4.2	3.2 to 5.3	58	5
Osteoarthritis	40	2.7	1.9 to 3.6	38	2
Microcrystalline arthritis	7	0.5	0.2 to 0.9	6	1
Arthritis	20	1.4	0.9 to 2.1	18	2
Extra-articular disorders	70	4.6	3.6 to 5.7	44	26
Tendonitis	67	4.4	3.4 to 5.5	44	23
Capsulitis	2	0.1	0.0 to 0.3	0	2
Carpal tunnel syndrome	2	0.1	0.0 to 0.3	0	2

\*Rates per 100 person-years of exposure.

analysis of each QoL dimension score as a dependent variable.

Two levels of type 1 error threshold were used: 10% in univariate analysis to select candidate variables for adjustment in the multivariate analysis, and 5% to determine statistical significance in the multivariate analysis.

Statistical analysis was performed using the SAS system (version 8.2).<sup>12</sup>

## RESULTS

Of 3759 eligible subjects, a total of 2557 (68%) respondents reported previous MSK disorders at inclusion, leaving 1202 MSK disorder-free subjects to participate in the longitudinal QoL study. Table 1 presents the sociodemographic characteristics of the subjects in this group who developed MSK and MSK disorder-free controls matched for age and sex. Their mean age was 51.1 years, and 37% were women. Differences appeared only for living alone ( $p = 0.07$ ), cancer ( $p = 0.08$ ), infectious disease ( $p < 0.0001$ ). MSK occurrence did not differ according to antioxidant or placebo allocation group ( $p = 0.26$ ). Average (SD) follow up was 28 (2.8) months, during which time 892 subjects remained healthy and 310 reported onset of one or more MSK conditions. The 310 subjects in the MSK disorder group were then randomly matched for age and sex with 620 out of 892 healthy controls for further analysis.

Reports of onset of an MSK disorder (table 2) in the follow up period reached 17.4 per 100 person-years of exposure. Most were spinal conditions, with an incidence of 13.6 per 100 person-years (predominantly back pain at 8.5 per 100 person-years) then extra articular disorders (4.6 per 100 person-years).

The first event in each category and subcategory was taken into account in calculating the incidence. If an event—for instance, back pain, occurred before another event—for instance, arthritis, only the first event—that is, back pain, was taken into account in the sum total of the MSK diseases.

Fewer subjects reported chronic rather than acute MSK disorders, whether unique or repeated (57 versus 173, respectively, in the spine pain category, 5 versus 58 in the joint category (osteoarthritis cases are mostly osteoarthritis flares), and 26 versus 44 in the extra-articular category).

Table 3 gives adjusted mean QoL scores in both groups, and the differences in change in scores over time. Baseline scores were similar in the two groups. At follow up in the MSK disorder group, only the bodily pain score had significantly decreased (a 10 point loss). The MSK disorder group exhibited a greater decrease than controls in scores for:

physical functioning (−1.2 between-group difference in within-group change), bodily pain (−7.4), vitality (−2.6), and general health (−1.8).

Within the MSK disorder group, changes in QoL over time differed between subjects who had an acute condition and those whose problem was chronic (table 4). The mean time between QoL assessment and the first report of a chronic condition was 17 months, and that for the last report of an acute condition was 15 months. Table 4 illustrates QoL scores adjusted for age, sex, living alone, infectious and cancer comorbidities at baseline and disclosed during follow up. The times between the report of an MSK disorder and QoL assessment, reductions in scores for physical functioning, role emotional, and social functioning dimensions were greater in the chronic subgroup, with a significant difference in QoL change between the subgroups (−2.2, −8.4, and −5.9, respectively). Between-group differences in the change in bodily pain and vitality dimension scores did not reach significance (−3.9 versus acute,  $p = 0.16$  and −2.5,  $p = 0.13$ , respectively). SF-6D utility scores did not differ either between groups or over time (tables 3 and 4).

## DISCUSSION

This inception cohort study confirms previous cross sectional results<sup>13–14</sup> that onset of an MSK disorder reduces QoL. The bodily pain dimension is most affected, with a 10 point loss on a 0–100 scale over 28 months of follow up. According to Ware *et al*, a five point difference is sufficient to reflect clinically and socially relevant change.<sup>15</sup> It confirms a cross sectional Dutch study results which showed a worse QoL in people with MSK diseases than in the general population, typically in physical dimensions of SF-36, with greater decrease with the coexistence of more than one MSK disease.<sup>16</sup> SF-36 physical dimension scores were slightly lower than ours. This may well reflect the prevalent cases—that is, established diseases in which the disease impact is more severe than in incident cases—that is, with recent onset or occurrence.

To our knowledge, this study is the first longitudinal comparison between subjects with and without onset of MSK disorders, of QoL data collected from the same subjects before and after onset of an MSK disorder. Use of MSK disorder-free controls matched for age and sex strengthens the conclusions drawn.

Efforts were made to ensure that the incidence of MSK disorders in the study sample was representative of the general population. Indeed, many eligible subjects ( $n = 2257$ ) had already had such a condition. Others have published

**Table 3** Change in QoL scores (SF-36) in MSK disorder (n = 310) and MSK disorder-free (n = 620) groups over the follow up period

	MSK disorder			MSK disorder-free			Difference in change		
	Baseline		Follow up	Baseline		Follow up	Mean ‡		p Values
	Mean*	95% CI		Mean*	95% CI		Mean ‡	95% CI	
Physical functioning	94.5	92.3 to 96.7	92.8	94.5	92.3 to 96.7	94.0	-1.2	-2.6 to -0.01	0.047
Role physical	87.9	83.2 to 92.6	83.1	87.6	83.0 to 92.2	85.2	-2.4	-6.1 to 1.5	0.23
Bodily pain	85.4	81.5 to 89.4	75.4	86.3	82.4 to 90.2	83.7	-7.4	-10.1 to -4.5	<0.0001
Mental health	70.7	66.8 to 74.5	70.8	70.7	66.8 to 74.5	71.8	-1.0	-3.0 to 1.1	0.35
Role emotional	87.7	81.9 to 93.5	84.1	86.5	80.7 to 92.3	85.2	-2.3	-6.2 to 1.9	0.34
Social functioning	82.5	78.1 to 86.8	81.9	83.3	79.0 to 87.6	84.2	-1.5	-4.4 to 1.1	0.24
Vitality	66.8	63.3 to 72.0	65.9	66.5	62.0 to 69.7	68.2	-2.6	-4.8 to -0.9	0.005
General health	74.2	70.4 to 78.0	73.6	73.4	69.6 to 77.2	74.6	-1.8	-4.0 to 0.2	0.03
SF-6D utility score (×100)	77.5	75.2 to 79.8	76.4	78.0	75.6 to 80.3	77.8	-0.9	-2.4 to 0.42	0.17

\*Mean scores adjusted for age, sex, living alone, and comorbidity (cancer and infectious disease), ranging from 0 (worst) to 100 (best).

†Baseline comparison between MSK disorder group and control group QoL means.

‡Change in mean score (baseline to follow up) in MSK disorder group minus change in mean score (baseline to follow up) in MSK disorder-free group.

§Test of interaction between time and group from a linear mixed model adjusted for age, sex, living alone, cancer, and infectious disease.

**Table 4** Changes in acute (n = 181) and chronic (n = 129) MSK disorder related QoL scores (SF-36) over the follow up period

	Chronic			Acute			Difference in change		
	Baseline		Follow up	Baseline		Follow up	Mean†		p Value‡
	Mean*	95% CI		Mean*	95% CI		Mean†	95% CI	
Physical functioning	94.8	91.4 to 98.1	91.8	95.1	91.6 to 98.5	94.3	-2.2	-4.2 to -0.1	0.04
Role physical	87.1	80.3 to 93.9	79.7	85.2	78.3 to 92.0	82.2	-4.4	-12.4 to 1.5	0.22
Bodily pain	85.5	79.6 to 91.3	73.3	86.9	80.9 to 92.9	78.6	-3.9	-9.9 to 0.7	0.16
Mental health	71.9	66.7 to 77.0	70.8	69.8	65.7 to 75.9	71.0	-2.3	-6.1 to 0.9	0.21
Role emotional	89.0	81.0 to 97.0	80.6	88.7	80.5 to 96.9	88.7	-8.4	-16.0 to -1.8	0.02
Social functioning	83.8	77.7 to 89.8	79.9	81.0	74.8 to 87.2	83.0	-5.9	-11.4 to -1.5	0.02
Vitality	66.3	60.9 to 71.7	63.9	66.4	60.8 to 71.9	66.5	-2.5	-6.1 to 0.5	0.13
General health	74.9	69.7 to 80.2	73.7	75.7	70.3 to 81.1	75.5	-1.0	-4.7 to 1.8	0.47
SF-6D utility score (×100)	76.8	73.6 to 79.9	74.2	77.3	74.2 to 80.8	76.8	-2.1	-4.3 to 0.8	0.17

\*Mean adjusted for age, sex, living alone, time between disorder onset, and QoL assessment at follow up, cancer, and infectious disease, ranging from 0 (worst) to 100 (best).

†Change in mean score (baseline to follow up) in chronic MSK disorder group minus change in mean score (baseline to follow up) in acute group.

‡Test of interaction between time and group from a linear mixed model adjusted (see \* above).



similar findings; for example, Hagen *et al* reported a prevalence of 60.8% among Norwegian adults in 1997.<sup>17</sup>

Moreover, the inclusion criteria applied here allowed for the identification of truly new cases, thus making it possible to calculate incidence rates and gain more information about within-subject changes in QoL over time.

In this 45–60 year age-group, the incidence of 17.4 per 100 person-years of exposure (time to occurrence) for any MSK disorder, and the annual incidence of back pain of 8.5 per 100 person-years, is within the range reported by previous European investigators. However, published estimates of the incidence of back pain vary widely. A Dutch study put it at 2–11% a year, depending on age<sup>18</sup>; a prospective study from Denmark reported a figure of 6%<sup>19</sup>; and a Swedish study estimated the monthly incidence to be 2.1%.<sup>20</sup> Tendonitis and back pain are the most common, which is similar to the results from Picavet and Hazes of a higher incidence of tendonitis, capsulitis, and herniated discs between the ages of 45 and 64.<sup>21</sup>

Although MSK conditions rarely cause death and are only seventh in the numbers of patients admitted to hospital, they are fifth for drug costs, third for chronicity, second for total health costs, first for health professional consultations, and are the most common disabling conditions in Western countries.<sup>22</sup> World wide, the proportion of the population disabled by rheumatism ranges from 2.8% in the United States to 8% in Great Britain.<sup>23–25</sup> In Canada, MSK problems accounted for 1.7% of the 1986 gross national product, a higher figure than that for cancer.<sup>26</sup>

The longitudinal design of the present investigation allowed for the identification of subjects remaining free from MSK disorders over time, and for their QoL to be measured at baseline and follow up. Another strength of the protocol is that subjects and controls were matched for age and sex. This is important because age and sex are confounding factors. Most QoL dimension scores relevant here decrease with age among adults and are lower in women than men. Furthermore, MSK disorders tend to increase in prevalence with age, and are subject to sex differences.<sup>27</sup> Mean baseline SF-36 scores were similar in the MSK disorder and control groups. Consequently, differences at follow up, after adjustment for comorbidity present at baseline or shown during follow up, can be expected to truly reflect the impact on QoL of MSK disorders, and allow its magnitude to be assessed.

The use of a generic instrument in the present survey is justified by the fact that it was carried out in an initially MSK disorder-free general population.

This study has several limitations. The reliability of self reporting of symptom and disease occurrence by questionnaire has some limitations that may affect the accuracy of recorded incidence of MSK disorders. Onset of symptoms is more likely reported than diagnosis, on the one hand, and some disorders already affecting patients at entry might have been omitted, on the other.

Consequently, the data gathered here cannot readily be compared with the findings of epidemiological studies using medical (ICD-10) taxonomy. Nevertheless, prevalence figures calculated from self reported information correlate with abnormalities observed by physicians.<sup>28</sup> Moreover, because subjects may fail to self report a disorder repeatedly as it becomes chronic, there may be a tendency to underestimate the incidence of chronic disease and misclassify certain conditions. Another reason is that we consider healthy subjects and that reported manifestations are early symptoms of conditions (acute or chronic).

The mid-life age group of the study sample (45–60 years), in which 80% of subjects were still professionally active, might limit the generalisability of the present findings and the comparability with other population surveys on the

occurrence of MSK. However, the levels of comorbidity in such populations are moderate and offer an opportunity to study the specific influence of MSK disorders on QoL with little interference from other diseases. MSK conditions, at least chronic ones, are relatively rare among subjects under 45, whereas people over 60 are more likely to have comorbidities with an influence on QoL. Older people are also more likely to live alone, have a low income, and be physically inactive.

Furthermore, as disorders were reported at regular intervals over the follow up period rather than as they occurred, acute conditions were more likely than chronic ones to be missed.

Although chronic disorders are well known to influence the psychosocial dimensions of the QoL,<sup>3</sup> we found a low relative impact on mental and social functioning that may be attributable to the predominance of acute disorders. Comparison between acute and chronic MSK conditions bears this out: a significant between-group difference in change in SF-36 social functioning and role emotional dimensions was noted (the greater reduction was in chronic conditions), but the mental health dimension scores were close to those in normal subjects, as previously reported.<sup>13</sup> The comparison of SF-6D utility scores between groups is limited by the use of English population weightings, which were the only ones available at this time.

Data on mean changes in QoL due to MSK disorders and baseline variance will help estimate the number of subjects required in future MSK prevention trials.

In conclusion, this inception investigation demonstrates that onset of an MSK disorder influences QoL. The physical domain is predominantly affected, but mental and social function are also impaired in comparison with control group findings. This evidence of an early significant impact on their QoL reinforces recent recommendations for early treatment and primary prevention.

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